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PATENT AND  
TRADEMARK OFFICE

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UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY  
AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
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In re Application of	:
David S. Garvey et al	:
Serial No.: 09/478,222	: PETITION DECISION
Filed: January 5, 2000	:
Attorney Docket No.: 102258.346	:

This is in response to applicants' petition under 37 CFR 1.144, filed September 26, 2001, requesting withdrawal of an improper restriction requirement. The delay in acting on this petition is regretted.

#### BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 111 on January 5, 2000, and is a DIV of 09/145,143, filed September 1, 1998, which is a CIP of 08/714,313, filed September 18, 1996, which is a CIP of 08/595,732, filed February 2, 1996, and a CIP of PCT/US97/01294. The application, as amended by preliminary amendment, contains claims 35-69. The examiner set forth in a first Office action, mailed March 22, 2001, a restriction requirement of the claims, as follows:

- Group I - claims 35-42, drawn to compositions containing NO containing compounds;
- Group II - claims 43-47, drawn to compositions comprising endogenous NO producing compounds;
- Group III - claims 48-52, drawn to compositions comprising 2-hydroxy-2-nitrosohydrazine;
- Group IV - claims 53-56, drawn to compositions comprising (E)-alkyl-2-((E)-hydroxyimino)-5-nitro-3-hexene amine/amide;
- Group V - claims 57-60, drawn to compositions comprising a "sydnonimine compound";
- Group VI - claims 61-65, drawn to compositions comprising S-nitrosothiol compounds;
- Group VII - claims 66-69, drawn to compositions comprising NONOate.

It is noted that all claims are to methods of using the compounds/compositions above.

The examiner stated that Groups I-VII are directed to methods which require the use of different bioactive compounds which are differently classified and would necessitate different burdensome searches. Further, the examiner required an election of species within the compounds of whichever Group was elected and requested a structural formula thereof, if appropriate.

Applicants replied by electing Group VI and the species S-nitroso-glutathione, presenting a structural formula thereof, and traversing the restriction requirement as not warranted based on the concept that all compositions were directed to the same type of compound (nitric oxide donating) and that no restriction requirements in parent applications were made such that similar types of nitroso and nitrosylated compounds were examined together. Those applications were examined by the same examiner. Also that no election of species was required in the parent applications.

The examiner accepted the election and replied to the traverse on June 29, 2001, explaining that the parent applications were directed to combinations of compounds forming compositions whereas the present application is directed to specific single compounds. The examiner further noted that election of species was required in some previous applications. The restriction requirement was maintained and made Final. Claims 61-65 were indicated as being examined. The examiner rejected claims 61-65 under 35 U.S.C. 112, first paragraph, as containing subject matter not described in the specification, but contained in a preliminary amendment filed with the application, but which was not referred to in the supplied declaration. The claims were rejected under 35 U.S.C. 103(a) as unpatentable over Stamler et al and Gioco et al. The claims were further rejected for obvious double patenting over SN 09/354,424 and SN 09/280,540 and SN 09/306,809, each in view of Stamler et al and Gioco et al.

Applicants replied on September 28, 2001, maintaining the traversal of the restriction requirement by the filing of this petition, responding to each of the rejections appropriately and by filing a terminal disclaimer.

## DISCUSSION

Applicants argue that restriction is improper when, as here, the claims are closely related. Applicants argue that all compounds are related as being nitric oxide donating compounds. Applicants argue that the examiner has not shown that the claims are separately classified, have acquired a separate status in the art or require a different field of search to show an undue burden on the Office. Applicants refer to two specific earlier applications issued by the same examiner in which nitrosated or nitrosylated compounds in combination with all nitric oxide donors were allowed without restriction of the nitric oxide donors as precedent for not requiring restriction.

Applicants' argument as to lack of showing of an undue burden is in error as the examiner in making the restriction requirement did show different classifications for the seven groups of claims. While the classifications are all within the same class, the subclasses are widely different, thus requiring a different required search for each group. The examiner is not required to show that all three conditions noted above are satisfied, only that at least one is satisfied.

M.P.E.P. 803.02 in examining the elected species and determining its patentability. If the species is determined to be patentable, the search and examination will be expanded to additional species. No error on the part of the examiner is seen in requesting an election of species as a starting point for examination of the application.

#### DECISION

Applicants' petition with respect to withdrawal of the restriction requirement is **DENIED**.

**The application will be forwarded to the examiner for consideration of applicants' reply to the last Office action following mailing of this decision.**

Any request for reconsideration or review of this decision must be by way of a renewed petition and must be filed within TWO MONTHS of the mailing date of this decision in order to be considered timely.

Should there be any questions with respect to this decision, please contact William R. Dixon, Jr., by mail addressed to: Director, Technology Center 1600, Washington, D.C. 20231, or by telephone at (703)308-3824 or by facsimile transmission at (703) 305-7230.



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